IMMUCELL CORP /DE/
Form 10-K
March 22, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

001-12934

(Commission file number)

ImmuCell Corporation

(Exact name of Registrant as specified in its charter)

Delaware	**01-0382980**
(State of incorporation)	**(I.R.S. Employer Identification No.)**

56 Evergreen Drive, Portland, Maine 04103

(Address of principal executive office) (Zip Code)

Registrant's telephone number: (207) 878-2770

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.10 per share

(Title of class)

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No þ

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No þ

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes þ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company þ
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes No þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates at June 30, 2018 was approximately $31,531,000 based on the closing sales price on June 29, 2018 of $6.82 per share.

The number of shares of the Registrant’s common stock outstanding at March 18, 2019 was 5,573,231.

Documents incorporated by reference: Portions of the Registrant’s definitive Proxy Statement to be filed in connection with the 2019 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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ITEM 1 – BUSINESS

Cautionary Note Regarding Forward-Looking Statements (Safe Harbor Statement):

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: our plans and strategies for our business; projections of future financial performance; the value of our deferred tax assets; projections about depreciation expense and its impact on income for book and tax return purposes; the scope and timing of ongoing and future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis; the expected efficacy of new products; estimates about the market size for our products; future market share of and revenue generated by current products and products still in development; our ability to increase production output and reduce costs of goods sold associated with our new product, **Tri-Shield First Defense®**; the future adequacy of our own manufacturing facilities or those of third parties with which we have contractual relationships to meet demand for our products on a timely basis; the continuing availability to us on reasonable terms of third-party providers of critical products or services; the robustness of our manufacturing processes and related technical issues; estimates about our production capacity; the future adequacy of our working capital and the availability and cost of third-party financing; the timing and outcome of pending or anticipated applications for regulatory approvals; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; future cost of our variable interest rate exposure on most of our bank debt; costs associated with sustaining compliance with current Good Manufacturing Practice (cGMP) regulations in our current operations and attaining such compliance for the facility to produce the Drug Substance; factors that may affect the dairy and beef industries and future demand for our products; implementation of international trade tariffs that could reduce the export of dairy products, which could in turn weaken the price received by our customers for their products; our effectiveness in competing against competitors within both our existing and our anticipated product markets; the cost-effectiveness of additional sales and marketing expenditures and resources; anticipated changes in our manufacturing capabilities and efficiencies; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as "expects", "may", "anticipates", "aims", "intends", "would", "could", "should", "will", "plans", "believes", "estimates", "targe "forecasts", "seeks" and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products (including **First Defense®** and **Re-Tain™**), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand, our reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory authorities, possible dilutive impacts on existing stockholders from any equity financing transactions in which we may engage, currency values and fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current

Reports on Form 8-K. Such statements involve risks and uncertainties and are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized under **Part I, Item 1A** — "Risk Factors" of this Annual Report and uncertainties otherwise referred to in this Annual Report.

Summary

ImmuCell Corporation was founded in 1982 and completed an initial public offering of common stock in 1987. After achieving approval from the Center for Veterinary Biologics, U.S. Department of Agriculture (USDA) to sell **First Defense**® in 1991, we focused most of our efforts during the 1990's attempting to develop human product applications of the underlying milk protein purification technology. Beginning in 1999, we re-focused our business strategy on the **First Defense**® product line and other products that improve the health and productivity of dairy and beef cattle. The demand for animal protein, that must be produced efficiently while ensuring food quality and safety, increases as the human population grows. Further, our products help address the growing human health concern about using less antibiotics in food-producing animals. We aim to capitalize on the growth in sales of the **First Defense**® product line (a product that provides significant **Immediate Immunity™** to newborn dairy and beef livestock) and to revolutionize the mastitis treatment paradigm with **Re-Tain™** (formerly **Mast Out**®), a product we are developing to treat this most significant cause of economic loss to the dairy industry.

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During 2000, we began the development of **Re-Tain™**, our purified Nisin treatment for subclinical mastitis in lactating dairy cows. No sales of this product can be made without prior approval of our New Animal Drug Application (NADA) by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA). We have now achieved FDA approval for four out of five of the significant regulatory submissions required for product approval. Regulatory achievements to date have significantly reduced the product development risks in the areas of safety and effectiveness. Our primary product development focus has now turned to completion of the manufacturing objectives required for FDA approval.

Since 2006, we have made ongoing efforts to maintain compliance with current Good Manufacturing Practice (cGMP) regulations in all of our manufacturing operations, which requires a sustained investment that further enhances the quality of all of our products and our operating efficiency. As we make process improvements, we continue to invest in personnel, equipment and facility modifications to increase the efficiency and quality of our operations.

To provide a portion of the funding needed for the development of **Re-Tain™** and expansion of the **First Defense®** product line, we issued an aggregate of 2,401,497 shares of common stock, raising gross proceeds of approximately $13.46 million in four separate transactions during 2017 and 2016. In order to minimize the dilutive effects of these transactions on our existing stockholders, we chose not to issue any form of convertible or preferred securities and issued these common shares without any warrants. During 2017 and 2016, we also secured approximately $6.8 million in new debt. We have invested this new capital to complete the development of **Re-Tain™** without relying on funding from a partner or licensee, thereby keeping control over all product rights and potential revenues.

Our operations have been generally profitable, except when we have elected to make unusually large investments in product development expenses for future growth. During the twenty years in which we have focused on products for the dairy and beef industries, we have funded our operations and improved our net financial position, as demonstrated in the following table (in thousands, except for percentages):

	As of December 31, 1998		Net Increase Over Twenty-Year Period		As of December 31, 2018	Net % Increase Over Twenty-Year Period
Cash, cash equivalents, short-term investments and long-term investments	$ 1,539	+	$ 982	=	$ 2,521	64 %
Net working capital	$ 1,866	+	$ 1,990	=	$ 3,856	107 %

Total assets	$ 3,145	+	$ 29,586	=	$ 32,731	941 %
Stockholders' equity	$ 2,248	+	$ 19,496	=	$ 21,744	867 %
Market capitalization	$ 3,036	+	$ 36,225	=	$ 39,261	1,193 %
Common shares outstanding(1)	2,429	+	3,140	=	5,569	129 %

(1) There were approximately 250,000 and 394,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2018, respectively.

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Animal Health Products

The **First Defense**® product line is manufactured from hyperimmune cows' colostrum (the antibody rich milk that a cow produces immediately after giving birth) utilizing our proprietary vaccine and milk protein purification technologies. The **First Defense**® product line provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. The target disease, calf scours (bovine enteritis), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. The **First Defense**® product line is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli* K99, coronavirus and rotavirus (three leading causes of scours). A single dose of our product provides a guaranteed level of protection proven to reduce mortality and morbidity. Our milk antibody products provide **Immediate Immunity™** during the first few critical days of life when calves need this protection most. Studies have shown that calves that scour are more susceptible to other diseases later in life and under-perform calves that do not contract scours. The direct, two-part mode-of-action of the **First Defense**® product line delivers specific immunoglobulins at the gut level to immediately protect against disease, while also providing additional antibodies that are absorbed into the bloodstream. These circulating antibodies function like a natural timed-release mechanism, as they are re-secreted into the gut later to provide extended protection. The **First Defense**® product line is convenient to use. A calf needs to receive only one dose of **First Defense**® within the first twelve hours after birth. The capsule format of this product is stored at room temperature and no mixing is required before it is given to the calf. The gel tube formats of this product require refrigeration in accordance with product label indications. We are a leader in the scours prevention market with this product. The third quarter of 2018 marked the 27th anniversary of the original USDA approval of this product in 1991. During the fourth quarter of 2018, our cumulative sales of **First Defense**® since inception exceeded 22,000,000 doses. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product.

We believe that the long-term growth in sales of the **First Defense**® product line may reflect, at least in part, the success of our strategic decision initiated in 2010 to invest in additional sales and marketing efforts to help us introduce the expanding **First Defense**® product line to new customers. We launched a communications campaign at the end of 2010 that continues to emphasize how the unique ability of the **First Defense**® product line to provide **Immediate Immunity™** generates a dependable and competitive return on investment for dairy and beef producers. Preventing newborn calves from becoming sick helps them to reach their genetic potential and reduces the need to use treatment antibiotics later in life.

Our new product line extension, **Tri-Shield First Defense®**, is the first calf-level, passive antibody product on the market with USDA-approved disease claims providing **Immediate Immunity™** against each of the three leading causes of calf scours (*E. coli*, coronavirus and rotavirus). This new product achieved USDA approval during the fourth quarter of 2017 and was listed with the Organic Materials Research Institute (OMRI) during the first quarter of 2019, which means it can be used on organic farms. **Tri-Shield®** combines the *E. coli* and coronavirus antibodies contained

in our bivalent product with a guaranteed level of rotavirus antibody in one preventative dose in a gel tube delivery format. This unique breadth of claims further differentiates our product from competitive products on the market that contain only one or two of these label claims. Because it is possible that all farms may not have a rotavirus problem, we are continuing to sell the bivalent formats of the **First Defense®** product line as options for customers.

Historically, the primary tool to help combat scours has been to vaccinate the cow with a dam-level scours vaccine. With this expanded claim set, we believe we can compete more effectively against these dam-level vaccine products that are given to the mother cow to increase the antibody level against specific scours-causing pathogens in the colostrum that she produces for her newborn. It is generally believed that only 80% of animals respond to a vaccine, which could leave about 20% of calves unprotected. We believe that the variability in a cow's immune response to vaccines creates a sales opportunity for our product. Additionally, our research suggests that treatment protocols for dam-level scours vaccine programs are not always followed, leaving even more calves compromised. Our new marketing campaign, **Beyond Vaccination®**, emphasizes that by delivering **Immediate Immunity™** directly to the calf via **Tri-Shield®**, producers can reduce stress-causing injections to the cow and save the associated labor for vaccines that are more critical to cow health. Reliance on a dam-level scours vaccine requires that money be spent before it is known whether the cow is carrying a viable, valued calf. With **Tri-Shield®**, every calf is equally protected and that investment can be targeted to the calves that are most critical to the operation. This, in turn, can free up space in the cow's vaccination schedule to improve her immune response to vaccines that are critical to her health.

First Defense Technology® is a unique whey protein concentrate that is processed utilizing our proprietary colostrum (first milk) protein purification methods, for the nutritional and feed supplement markets without the claims of our USDA-licensed product. During 2012, we initiated a limited launch of a gel tube delivery format of our **First Defense Technology®** in a gel solution. We achieved USDA claims for this product format during the fourth quarter of 2018 and Canadian approval during the first quarter of 2019, and it is now being sold as **Dual-Force™ First Defense®**. We are selling the same concentrated whey proteins in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding to calves. We are working to achieve USDA claims for this product format during 2019. During 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start® 150 Plus and certain similar private label products, which are colostrum replacers with **First Defense Technology® Inside**.

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Other competition for resources that dairy producers allocate to their calf enterprises has been increased by the many new products (principally feed supplements) that have been introduced to the calf market. Warm and dry weather reduces the producer's perception of the need for a disease preventative product like the **First Defense®** product line. However, heat stress on calves caused by extremely hot summer weather can increase the incidence of scours, just as harsher winter weather benefits our sales. Market conditions in the dairy and beef industries, including milk pricing and prices for calves, have weakened since 2014. Milk prices made modest improvements in 2017 over the annual averages for 2016 and 2015 but declined by 10% in 2018 in comparison to 2017. Despite the significant market volatility affecting both milk prices and feed costs, we continue to increase our sales.

During the first quarter of 2017, we discontinued the topical wipes product line due to its limited sales growth potential and minimal contribution to profits.

During 2001, we began to offer our own, internally developed **California Mastitis Test (CMT)**. **CMT** is most often used as a quick on-farm diagnostic to determine which quarter of the udder is mastitic. This test can be performed at cow-side for early detection of mastitis. **CMT** products are also made by other manufacturers and are readily available to the dairy producer.

In connection with our acquisition of certain gel formulation technologies during the first quarter of 2016, we also acquired private label manufacturing rights covering two feed supplement product lines that we now produce and sell under private label relationships with Ridley, USA Inc. of Mankato, MN and Genex Cooperative Inc. of Shawano, WI. These products do not utilize our proprietary antibody technology.

Sales and Markets

Our sales and marketing team consists of one vice president, seven regional manager positions and one inside sales and marketing position. The **First Defense®** product line and **CMT** are sold primarily through major animal health distributors who, in turn, sell to veterinary clinics, fleet stores and direct to farms. We have experienced minimal bad debt with respect to these products. Sales of the **First Defense®** product line are normally seasonal, with higher sales expected during the first quarter, largely driven by the beef calving season, which runs primarily from January to April, unlike the dairy industry in which operations generally calve year round.

We estimate that the total U.S. market for scours preventative products (including sales of our product) that are given to newborn calves (the calf-level market) is approximately $18 million annually. With the additional claim for our new product (**Tri-Shield First Defense**®) against rotavirus, we are now competing against the dam-level vaccine products that are given to the mother cow to increase the antibody level against specific scours-causing pathogens in the colostrum that she produces for her newborn. We estimate that the dam-level product category covers approximately twice as many calves as the calf-level product segment reaches.

The majority of our international sales are to Canada. We price our products in U.S. dollars. To the extent that the value of the dollar declines with respect to any other currency, our competitive position may be enhanced. Conversely, an increase in the value of the dollar in any country in which we sell products may have the effect of increasing the local price of our products, thereby leading to a potential reduction in demand. Generally, our international sales have been generated through relationships with in-country distributors that have knowledge of the local regulatory and marketing requirements. We are initiating our plan to expand the number of countries to which our **First Defense**® product line is approved for export. Generally, it is our intent to be the holder of these product registrations for each country rather than rely on distribution partners to gain and hold these registrations. This is a long regulatory process but allows us to maximize the use of our product label claims and avoid long-term exclusive distribution agreements. We continue our efforts to grow sales of the **First Defense**® product line in North America, where there are approximately 41,300,000 dairy and beef cows in the United States and 4,645,000 dairy and beef cows in Canada. We believe that even greater market opportunities exist in other international territories. There are estimated to be approximately 67,400,000 dairy and beef cows in China, 35,450,000 in the European Union, 18,470,000 in Australia and New Zealand, 11,150,000 in Mexico, 1,700,000 in South Korea and 1,470,000 in Japan. The statistics above are provided by an industry compilation of USDA data for 2019. However, industry practices, economic conditions, cause of disease, distribution channels and regulatory requirements may differ in these international markets from what we experience in North America making it more difficult or costly for us to generate and sustain sales volumes at profitable margins in these markets.

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We introduced **First Defense®** into South Korea in 2005 through Medexx Co., Ltd of Gyeonggi-do, Korea and its equivalent into Japan in 2007 through NYS Co., Ltd of Iwate, Japan. The business in Japan is currently not active, but we hope to resume sales in this territory in the coming quarters. We entered into distribution contracts covering certain Middle Eastern countries with Triplest for Drugs and Trade of Madaba, Jordan during the first quarter of 2017 and covering Iran with Senikco, LLC of Laguna Niguel, CA during the fourth quarter of 2016.

With **Re-Tain™**, we are working to expand our product offerings to include an intramammary treatment for subclinical mastitis for the mother cow during lactation. Mastitis (inflammation of the mammary gland) is estimated to cost the U.S. dairy industry approximately $2 billion in economic harm per year, which makes it the most costly and common disease affecting the dairy industry. The disease diminishes the saleable quantity and overall value of milk, in addition to causing other herd health and productivity losses. While the benefit of treating clinical mastitis is widely known, subclinical mastitis (those cases where cows have infected udders, but still produce saleable milk) is associated with its own significant economic losses and is recognized as a substantial contributor to clinical mastitis cases. There is a growing awareness of the cascade of adverse events and conditions associated with subclinical mastitis for both the dairy producer and the milk processor, including reduced or foregone milk quality premiums, lower milk production (some have estimated approximately 1,500 pounds of lost milk, or about $225 at $15.00 per hundredweight, per infected cow), shorter shelf life for fluid milk, lower yields and less flavor for cheese, higher rates of clinical mastitis, lower conception rates, increased abortions and increased cull rates. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry approximately $1 billion per year.

We believe that **Re-Tain™** could revolutionize the way that mastitis is treated by making earlier treatment of subclinically infected cows economically feasible by not requiring a milk discard during, or for a period of time after, treatment, which would be a significant competitive advantage for our product. No other FDA-approved mastitis treatment product on the market can offer this value proposition. Because the milk from cows treated with traditional antibiotics must be discarded, most dairy producers simply do not treat subclinically infected cows. It is generally current practice to treat mastitis only when the disease has progressed to the clinical stage where the milk from an infected cow cannot be sold. The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. It is common practice to move sick cows from their regular herd group to a sick cow group for treatment and the related milk discard. This movement causes stress on the cow and a reduction in milk production. Cows treated with our product would not have to be moved, allowing this costly drop in production to be avoided. Our product likely will be priced at a premium to the traditional antibiotic products currently on the market, which are all sold subject to a milk discard requirement. Common milk discard periods cover the duration of treatment and extend from 36 to 96 hours after last treatment, depending on the antibiotic. On average, a cow produces approximately 60 to 80 pounds of milk per day. While milk prices vary significantly, at an average value of $15.00 per 100 pounds, a cow produces approximately $9 to $12 worth of milk per day. These estimated figures would result in milk discard costs ranging from approximately $32 (for 3.5 days of milk at 60 pounds per day) to $132 (for 11 days of milk at 80 pounds per day) per treated animal. We estimate that the approximate cost to the U.S. dairy industry of this discarded milk may be around $300 million per year. We believe that the product's value proposition demonstrates a return on investment to the dairy producer and the milk processor that will justify a premium over other mastitis treatments on

the market today.

The USDA's National Animal Health Monitoring System through its Dairy 2014 study suggests that 21% of all dairy cows are treated with a mastitis drug, of which approximately 51% are treated with third generation cephalosporins. Many fear that the possible overuse of antibiotics in livestock undermines the effectiveness of drugs to combat human illnesses and contributes to a rising number of life-threatening human infections from antibiotic-resistant bacteria, commonly known as "superbugs". The FDA is committed to addressing this public health risk. Citing concerns about untreatable, life-threatening infections in humans, new FDA and European regulations are aimed at restricting the use of antibiotics (including cephalosporins) in food animals and at improving milk quality. Regulators have recently increased their monitoring of antibiotic residues in milk and meat. During the first quarter of 2012, the USDA reduced the allowable level of somatic cell counts (SCC) in milk from 750,000 (cells per milliliter) to 400,000 at the individual farm level (not a blended calculation of comingled milk) in order to qualify for an EU health certification for export.

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The FDA's Veterinary Feed Directive (VFD) became effective January 1, 2017, restricting the use of medically important antibiotics for performance purposes and requiring more oversight of antibiotic usage in food producing animals by a veterinarian, and more changes and restrictions relating to antibiotic usage appear to be likely. Several major food processors and retailers have implemented policies addressing this growing public health concern. By reducing the risk of antibiotic residues and slowing the development of antibiotic-resistant organisms, we can improve food quality and preserve medically important antibiotics for human disease treatment. This would not be a concern for **Re-Tain™** because Nisin is not used for human health. This current environment could be favorable to the introduction of our new product as an alternative to traditional antibiotics such as penicillin and cephalosporins. We believe that this changing environment of new regulations and public opinion supports the value of our ongoing development and commercialization efforts for **Re-Tain™**. Additionally, we believe that the use of our **First Defense®** product line is consistent with this trend of reducing the use of antibiotics because the prevention of calf scours early in life with our purified colostrum antibodies can reduce the need for treatment antibiotics later in a calf's life.

It is difficult to estimate the potential size of the market for the treatment of subclinical mastitis because this disease is largely left untreated presently. We believe that approximately 20-30% of the U.S. dairy herd is affected by subclinical mastitis caused by Gram-positive organisms falling within the claim spectrum of our product. This compares to approximately 2% of the U.S. herd that is thought to be infected with clinical mastitis, where approximately $60 million per year is spent on drug treatments. We believe that similar market opportunities also exist outside of the United States and for the treatment of dry (non-lactating) cows. We expect the Drug Substance production facility that we constructed for approximately $20.8 million to have annual production capacity sufficient to meet approximately $10 million in sales of **Re-Tain™**. Our new facility is designed to have enough room to add a second fermentation and recovery portion of the production line to be purchased and installed at the cost of approximately $7 million to effectively double production output. We would consider making this investment only after commercial acceptance of the product is demonstrated. If annual sales exceed approximately $20 million with finished product filling services provided by a contractor, we would evaluate all Nisin supply options, factoring in efficiencies and yield improvements. Building an additional Drug Substance production facility to meet our needs at that time may be the most cost-effective solution. See additional disclosures about our manufacturing strategies and capacity under "Product Development" below.

With a measured approach to expanding our customer-facing staff, it is our objective to increase our current annual level of product sales of approximately $11 million to approximately $20 million through both continued growth in sales of the **First Defense®** product line and a successful launch of **Re-Tain™** as soon as possible. As market penetration for both new products is achieved and additional resources are dedicated to production, sales, marketing and technical services, our longer-term goal is to exceed the $30 million level of annual product sales as soon as possible during the five-year period after the market launch of **Re-Tain™**.

Product Development

The majority of our product development spending has been focused on the development of **Re-Tain**™, our purified Nisin treatment for subclinical mastitis in lactating cows. During the nineteen-year period that began on January 1, 2000 and ended on December 31, 2018, we invested the aggregate of approximately $15,543,000 (excluding depreciation and the capital cost of our Drug Substance production facility) in the development of this product. This estimated allocation reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately $2.9 million of this investment was offset by related product licensing revenues and grant income, most of which was earned from 2001 to 2007.

Nisin is a bacteriocin that is not used in human medicines and could alleviate some of the social concerns that the widespread use of antibiotics encourages the growth of antibiotic-resistant bacteria (“superbugs”). This antibacterial peptide is known to be effective against most Gram-positive and some Gram-negative bacteria. Mastitis, which costs the dairy industry about $2 billion per year, is currently treated with traditional antibiotic products, and treatment is generally reserved for clinical infections when the cow produces non-saleable milk. The “zero milk discard” product feature approved for **Re-Tain**™ would make earlier treatment of sick cows economically feasible, while these cows are still producing saleable milk. No other existing product can provide this kind of value proposition.

During 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Re-Tain™**. In 2004, we paid Nutrition 21 approximately $965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes processing and purification methods to achieve pharmaceutical-grade purity.

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In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health (now known as Zoetis) covering this product. That company elected to terminate the agreement in 2007. We believe that this decision was not based on any unanticipated efficacy or regulatory issues. Rather, we believe the decision was primarily driven by a marketing concern relating to their fear that the milk from treated cows could interfere with the manufacture of certain cultured dairy products. Due to the zero milk discard feature, there is a risk that Nisin from the milk of treated cows could interfere with the manufacture of certain (but not all) commercial cultured dairy products, such as some kinds of cheese and yogurt, if a process tank contains a high enough percentage of milk from treated cows. The impact of this potential interference ranges from a delay in the manufacturing process (which does happen at times for other reasons) to the less likely stopping of a cheese starter culture. Milk from cows that have been treated with our product that is sold exclusively for fluid milk products presents no such risk. We worked with scientists and mastitis experts to conduct a formal risk assessment to quantify the impact that milk from treated cows may have on cultured dairy products. This study concluded that the dilution of milk from treated cows through comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when the product is used in accordance with the product label. We do not believe that such a premium-priced product will be used as part of a whole herd ("blitz") treatment protocol, which reduces the risk of cheese interference. We do not see this as a significant problem as modern "precision dairying" practices, as well as cost and other economic considerations, support reducing the indiscriminate use of drug treatments.

The NADA for **Re-Tain™** is comprised of five principal Technical Sections and one administrative submission that are subject to phased review by the FDA. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. Each Technical Section can be reviewed and approved separately. Upon review and assessment by the FDA that all requirements for a Technical Section have been met, the FDA may issue a Technical Section Complete Letter. The current status of our work on these submissions to the FDA is as follows:

1) Environmental Impact: During the third quarter of 2008, we received the Environmental Impact Technical Section Complete Letter from the FDA.

2) Target Animal Safety: During the second quarter of 2012, we received the Target Animal Safety Technical Section Complete Letter from the FDA.

3) Effectiveness: During the third quarter of 2012, we received the Effectiveness Technical Section Complete Letter from the FDA. The draft product label carries claims for the treatment of subclinical mastitis associated with *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, and coagulase-negative staphylococci in lactating dairy cattle. In our pivotal effectiveness study, statistically significant cure rates were associated with a statistically significant reduction in milk somatic cell count, which is an important measure of milk quality.

4) Human Food Safety (HFS): During the third quarter of 2018, we received the Human Food Safety Technical Section Complete Letter from the FDA confirming, among other things, a zero milk discard period and a zero meat withhold period during and after treatment with our product.

5) Chemistry, Manufacturing and Controls (CMC): Obtaining FDA approval of the CMC Technical Section is the final critical step to FDA approval and to initial commercial sales. Implementing Nisin production at commercial scale, which is a required component of the CMC Technical Section, has been the most expensive part of this project. We previously entered into an agreement with a multi-national pharmaceutical ingredient manufacturer for our commercial-scale supplies of Nisin. However, we determined in 2014 that the agreement did not offer us the most advantageous supply arrangement in terms of either cost or long-term dependability. We presented this product development opportunity to a variety of large and small animal health companies. While such a corporate partnership could have provided access to a much larger sales and marketing team and allowed us to avoid the large investment in a commercial-scale production facility, the partner would have taken a large share of the gross margin from all future product sales of **Re-Tain™**. The regulatory and marketing feedback about the prospects for this product that we received from prospective partners, following their due diligence, was positive. During the third quarter of 2014, we completed an investment in facility modifications and processing equipment necessary to produce the Nisin Drug Substance (the active pharmaceutical ingredient) at small-scale. This small-scale facility was used to i) expand our process knowledge and controls, ii) establish operating ranges for critical process parameters, iii) conduct product stability studies, iv) optimize process yields and v) verify the cost of production. We believe these efforts have reduced the risks associated with our investment in the commercial-scale production facility. During the fourth quarter of 2015, we acquired land nearby to our existing Portland facility for the construction of a new commercial-scale Drug Substance manufacturing facility. We commenced construction of this facility during the third quarter of 2016 and completed construction during the fourth quarter of 2017. Equipment installation and qualification was initiated during the third quarter of 2017 and completed during the third quarter of 2018. The total cost of this building and equipment investment was approximately $20.8 million.

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We made our first phased Drug Substance submission to the FDA of this comprehensive and complex Technical Section during the first quarter of 2019. This Technical Section includes data from the Nisin Drug Substance Registration Batches produced at commercial scale in our new manufacturing facility. This submission is subject to a six-month review period. The timing of this first submission does not directly impact the regulatory timeline because the second phased Nisin Drug Product submission (which will include responses to the FDA review of the first phased submission and detailed information about the manufacturing process and controls for the sterile Nisin Drug Product) defines the critical path to product approval. A successful FDA inspection of our manufacturing facility must also be achieved. The second phased Drug Product submission, which is also subject to a six-month review period, will not be made in time to achieve product approval by our original goal of December 2019.

Since 2010, we have been a party to a long-term exclusive product development and contract manufacturing agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved Drug Product manufacturer, covering the final formulation, aseptic filling and final packaging services for **Re-Tain**™. Norbrook has provided services to us under this contract throughout the FDA process for use in all of our pivotal studies. During the fourth quarter of 2015, this agreement was amended and restated to, among other things, extend the term of the agreement to January 1, 2024. It has been our expectation that we would have these services available through both the remainder of the development process and approximately the first four years of commercial sales. However, the agreement includes a provision potentially entitling Norbrook to terminate the agreement if we fail to receive FDA approval for **Re-Tain**™ by mid-December of 2019. Due to unexpected difficulties and delays encountered by Norbrook at this late stage of the development and the usual FDA timeline for processing CMC Technical Sections, we do not expect to receive FDA approval by the December 2019 date.

In anticipation of this potential issue, we have made requests to Norbrook to amend the existing agreement to avoid early termination, including a shorter term and increased payments to Norbrook. However, we have not yet reached resolution on an amendment, and it remains unclear whether we will be able to reach agreement on a suitable amendment, or if we do, for how long we will continue to have access to Norbrook’s services. Consequently, we have been actively investigating multiple alternatives, including securing an agreement for such services with another qualified third party or performing the services in-house by constructing an aseptic filling capability within our new Drug Substance production facility. Because both of these alternatives would likely delay our commencement of commercial sales of **Re-Tain**™ to at least 2021, we believe, in the case of a new third-party manufacturer, and to at least 2022, we estimate, in the case of performing these services in-house, our strong preference would be to reach at least an interim arrangement with Norbrook, while we pursue the implementation of the chosen alternative in parallel.

The option of establishing our own final formulation, aseptic filling and final packaging capability for Drug Product would provide us with the longer-term advantage of controlling the entire manufacturing process for **Re-Tain**™ in one facility, thereby reducing our dependence on third parties and potentially reducing our manufacturing costs, but it would require us to raise additional capital to fund the cost of the equipment, facility modifications and related

validation process, which we estimate on a very preliminary basis to be approximately $4 million. This equipment would occupy space in our new Drug Substance facility that we had originally intended to use to double our Drug Substance manufacturing capacity if warranted by **Re-Tain**™ sales volumes during the initial years following product launch, as discussed above under “Sales and Markets”, thus limiting the maximum production capacity of our new Drug Substance facility. This could possibly leave us unable to meet growing customer demand for **Re-Tain™** until and unless we are able to expand that capacity elsewhere or otherwise relocate certain manufacturing activities to enable the expansion to occur.

After approval of the CMC Technical Section, there is a 60-day administrative review before anticipated product license approval can be issued and commercial sales can be initiated.

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We are party to a long-term, exclusive supply agreement with Plas-Pak Industries, Inc. (now owned by Nordson Corporation) of Norwich, Connecticut covering the proprietary syringe that was developed specifically for treating cows with our mastitis product. These syringes were used for all pivotal studies. During the third quarter of 2017, this agreement was extended to January 1, 2024.

Our second most important product development initiatives (in terms of dollars invested and, we believe, potential market impact) have been focused on other improvements, extensions or additions to our **First Defense®** product line. During the second quarter of 2009 we entered into an exclusive license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies for use with animals. This perpetual license (if not terminated for cause) is subject to ongoing royalty payments. We achieved product license approval and initiated market launch of this product, **Tri-Shield First Defense®**, during the fourth quarter of 2017. During the third quarter of 2018, we obtained approval from the Canadian Food Inspection Agency to sell **Tri-Shield®** in Canada. We expect to initiate sales in Canada after domestic demand is met. We achieved USDA approval of our bivalent gel tube formulation (formerly marketed as **First Defense Technology®**) during the fourth quarter of 2018 and have re-branded this product format, together with the bolus format, as **Dual-Force™ First Defense®.** We are currently working to establish USDA claims for our bivalent bulk powder formulation of **First Defense Technology®**. We are also investing in additional studies comparing the **First Defense®** product line to the competition.

At the same time, we are working to expand our product development pipeline of bacteriocins that can be used as alternatives to traditional antibiotics. During the second quarter of 2015, we entered into an exclusive option agreement to license new bacteriocin technology from the University of Massachusetts Amherst. During the first quarter of 2019, we extended this exclusive option agreement through March 2021. This technology focuses on bacteriocins having activity against Gram-negative infections for use in combating mastitis in dairy cattle. Subject to the availability of resources, we intend to begin new development projects that are aligned with our core competencies and market focus. We also remain interested in acquiring, on suitable terms, other new products and technologies that fit with our sales focus on the dairy and beef industries.

Competition

Our competition in the animal health market includes other biotechnology companies and major animal health companies. Many of these competitors have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do.

We would consider any company that sells an antibiotic to treat mastitis, such as Boehringer Ingelheim, Merck Animal Health and Zoetis (formerly Pfizer Animal Health, a division of Pfizer, Inc.), to be among the potential competitors with respect to **Re-Tain™**. We expect the FDA to grant a period of five years of market exclusivity for our product (meaning the FDA would not grant approval to a second NADA with the same active drug for a period of five years after the first NADA approval is granted) under Section 512(c)(2)F of the Federal Food, Drug, and Cosmetic Act.

There are several other products on the market (some with claims and some without) that are delivered to newborn calves to prevent scours. We believe that the **First Defense®** product line offers two significant competitive advantages. First, only the **First Defense®** product line provides protection against *E. coli,* coronavirus and rotavirus, three of the leading causes of calf scours. Second, being derived from colostrum, our product offers **Immediate Immunity™** through antibodies that both function at the gut level and are absorbed into the blood stream for future protection. All formats of our product can be administered without delaying or adversely affecting maternal colostrum.

Zoetis sells a product that competes directly with the **First Defense®** product line in preventing scours via oral delivery to newborn calves. Their product (Calf-Guard®) is a modified-live virus vaccine. Newborn calves respond poorly to vaccines and the immune system must be given time to develop a response to vaccines. Both our product and Calf-Guard® carry claims against coronavirus and rotavirus infections, but this competitive product does not carry a claim against *E. coli* infections like our product does. It is common practice to delay colostrum feeding when dosing a calf with Calf-Guard® so that the antibodies in the colostrum do not inactivate the vaccine product. There is no nutritional benefit to withholding milk from newborn calves. In contrast, we encourage the feeding of four quarts of high quality colostrum immediately after birth when dosing a calf with our product, which is standard practice for good calf health. Because the antibodies in our product would likely work to inactivate a modified-live vaccine, rendering it useless or less useful, our product label historically included a precaution that **First Defense®** should not be used within five days of such a vaccine. During the first quarter of 2015, the USDA granted us permission to remove this precaution from our label, and we have done so. We believe that this precaution should be required on the Calf-Guard® label to prevent inactivation of that product by **First Defense®** antibodies or colostrum. Our product is priced at a premium to Calf-Guard®.

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Elanco Animal Health (a division of Eli Lilly and Company) and Boehringer Ingelheim also sell directly competitive products. The Elanco product (Bovine Ecolizer® and Bovine Ecolizer® + C20) was acquired through Elanco's January 2015 acquisition of Novartis Animal Health and carries claims to prevent scours in newborn calves caused by *E. coli* and *C. perfringens*. The Boehringer product (Bar-Guard-99™) carries claims to prevent scours in newborn calves caused by *E. coli*. These two products are both derived from horse blood rather than the bovine colostrum used for the **First Defense**® product line. Equine antibodies are less efficiently absorbed into the bovine bloodstream, so fewer antibodies are re-secreted for additional protection.

During the fourth quarter of 2016, Merck launched a new competitive product into this market space. This product (BOVILIS® Coronavirus) is a modified-live virus intranasal vaccine that carries a claim against coronavirus only.

When compared to the other USDA-approved calf-level scours preventatives, we believe we are first in sales dollars and second in volume. This product category is comprised of five (increasing from four until the fourth quarter of 2016) primary brands that are given either orally or intranasal to newborn dairy and beef calves immediately after birth. Market research that we subscribe to suggests that our product comprised approximately 34% and 33% of the total doses sold in this product category (one dose equates to one calf, according to label administration on all products) during 2018 and 2017, respectively. These estimates are down from 36% during 2016 and 40% during 2015 when the product category included only 4 primary brands (one of which experienced lack of supply to the market during late 2014 and into the middle of 2015). This market share estimate is slightly up from 32% in 2014 and up from 26% and 22% in 2013 and 2012, respectively, as the total volume in the product category has steadily increased. These estimates do not include sales of vaccine products that are given to the dam (mother cow), which is discussed below.

With the new rotavirus claim for our product (**Tri-Shield First Defense**®) we are now competing against dam-level vaccine products that are given to the mother cow to increase the antibody level against scours-causing pathogens in the colostrum that she produces for her newborn. Those products are sold by Elanco (Scour Bos™), Merck (Guardian®) and Zoetis (ScourGuard®). Despite the best-managed dam vaccine program, colostrum quality is naturally variable and newborn calves do not always get the antibodies they need from maternal colostrum. We believe that the guaranteed dose of antibodies in our product provides more consistent protection than such vaccine products.

We may not be aware of competition that we face, or may face in the future, from other companies. Our competitive position will be highly influenced by our ability to attract and retain key scientific, managerial and sales personnel, to develop proprietary technologies and products, to obtain USDA, FDA or foreign approvals for new products, to effectively promote and market our products, to have available properly licensed, efficient and effective raw material and finished product manufacturing resources and to continue to profitably sell our current products. We currently

compete on the basis of product performance, price and distribution capability. We continue to monitor our network of independent distributors to maintain our competitive position.

Intellectual Property

We own a broad collection of intellectual property rights relating to our research, products and processes. This includes patents, copyrights, trademarks, trade dress, trade secrets, know-how and other intellectual property rights in the United States and other countries. While the Company believes the ownership of its intellectual property rights is an important factor in its business and that its success depends in part on such ownership, the Company also relies heavily on the innovative skills, technical competence and marketing abilities of its personnel.

We own: (a) U.S. Patent No. 6,794,181 entitled “Method of Purifying Lantibiotics”, which covers a manufacturing process for preparing pharmaceutical-grade Nisin, which was issued in 2004; and (b) U.S. Patent No. 10,023,617 entitled “Methods and Systems of Producing Pharmaceutical Grade Lantibiotics”, which covers key, novel and proprietary aspects of our manufacturing process for preparing pharmaceutical-grade Nisin, and was issued during the third quarter of 2018. In the future, we may file additional patent applications for certain products under development. There can be no assurance that patents will be issued with respect to any pending or future applications. In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. In those instances, we have sought (and may seek in the future) to maintain the confidentiality of any relevant intellectual property and other proprietary rights through operational measures and contractual agreements.

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We own numerous trademarks and trade dress that are very important to our business, and have several trademark and trade dress applications and registrations in the United States, Canada, Iran and Turkey. We own the following U.S. trademark registrations: **IMMUCELL**, **FIRST DEFENSE**, **FD FIRST DEFENSE (& Design), FIRST DEFENSE TECHNOLOGY**, **TRI-SHIELD FIRST DEFENSE, TRI-SHIELD FIRST DEFENSE (& Design), YOUR CALF CREW, BEYOND VACCINATION, BEYOND VACCINATION (& Design), CALF HERO** and **TRI-SHIELD.** We also own U.S. registrations for the color blue for our blue gel and blue bolus **FIRST DEFENSE** products. We own pending U.S. trademark applications for the **DUAL-FORCE** and **RE-TAIN** trademarks. The United States Patent and Trademark Office issued a determination that our **IMMEDIATE IMMUNITY** trademark, which we use in connection with marketing of all of our products, is generic. Rather than appeal this finding, we are continuing to build our common law rights in the brand. The FDA issued a determination that the name, **MAST OUT**, which we had intended to use for our purified Nisin product, is overly promotional. Rather than continuing an appeal of this decision, we selected a new product name, **RE-TAIN**, which was approved by the FDA during the first quarter of 2019. During the first quarter of 2017, we sold our registered trademarks related to dairy wipes, **WIPE OUT** and **THE ONE STEP COW PREP,** when we discontinued that product line.

Government Regulation

We believe that we are in compliance with current regulatory requirements relating to our business and products. The manufacture and sale of animal health biologicals within the United States is generally regulated by the USDA. We have received USDA and Canadian Food Inspection Agency approval for the bolus format of **First Defense®** and for the gel tube formats of **Tri-Shield First Defense®** and **Dual-Force™ First Defense® Re-Tain™** is regulated by the FDA, which regulates veterinary drugs. Regulations in the European Union will likely require that our product be sold subject to a milk discard requirement in that territory, although the duration of the milk discard requirement may be shorter than the discard requirement applicable to competitive antibiotic products in that market. Comparable agencies exist in foreign countries, and foreign sales of our products will be subject to regulation by such agencies. Many countries have laws regulating the production, sale, distribution or use of biological products, and we may have to obtain approvals from regulatory authorities in countries in which we propose to sell our products. Depending upon the product and its applications, obtaining regulatory approvals may be a relatively brief and inexpensive procedure or it may involve extensive clinical tests, incurring significant expenses and an approval process of several years' duration. We generally rely on in-country experts to assist us with or to perform international regulatory applications.

Employees

We currently employ 51 employees (including 4 part-time employees). Approximately 29 full-time equivalent employees are engaged in manufacturing operations, 9.7 full-time equivalent employees in sales and marketing, 6

full-time equivalent employees in product development activities and 4.3 full-time equivalent employees in finance and administration. As needed, we augment our staff with contracted temporary employees. At times, manufacturing personnel are also utilized, as needed, in the production of clinical material for use in product development. All of our employees are required to execute non-disclosure, non-compete and invention assignment agreements intended to protect our rights in our proprietary products. We are not a party to any collective bargaining agreement and consider our employee relations to be excellent.

Public Information

As a reporting company, we file quarterly and annual reports with the Securities and Exchange Commission (SEC) on Form 10-Q and Form 10-K. We also file current reports on Form 8-K, whenever events warrant or require such a filing. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information about us that we file electronically with the SEC at *http://www.sec.gov*. Our internet address is *http://www.immucell.com*.

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ITEM 1A — RISK FACTORS

Projection of net income (loss): Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Weaker than expected sales of the **First Defense®** product line could lead to less profits or an operating loss. Large investments in product development (or cost overruns) can result in a net loss. We were profitable during the second half of 2014, during the years ended December 31, 2015 and 2016 and during the nine-month period ended September 30, 2017. During the five quarters since then, we have incurred net losses largely due to facility start-up and development costs related to our Nisin product development program. Depreciation expenses related to the Drug Substance production facility are expected to contribute to reported net losses until and unless product sales increase to offset these non-cash expenses.

Deferred tax assets: The realizability of our deferred tax assets is a subjective estimate that is contingent upon many variables. During the second quarter of 2018, we recorded a full valuation allowance against our deferred tax assets that significantly increased our net loss in comparison to other periods. This non-cash expense could be reversed in the future if justified by current and near-term projections of profitability. We will continue to assess the need for the valuation allowance at each quarter, and in the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to adjust our valuation allowance.

*Reliance on sales of the **First Defense®** product line:* We are heavily reliant on the market acceptance of the **First Defense®** product line to generate product sales and fund our operations. Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007 or during the years ended December 31, 2012, 2013, 2015 and 2016 without the gross margin that we earned on sales of the **First Defense®** product line, which accounted for 97% and 94% of our total product sales during the years ended December 31, 2018 and 2017, respectively.

Concentration of sales: Approximately 100% and 98% of our product sales were made to customers in the dairy and beef industries throughout the world during the years ended December 31, 2018 and 2017, respectively. Approximately 87% and 82% of our product sales were made to customers in the U.S. dairy and beef industries during the years ended December 31, 2018 and 2017, respectively. The animal health distribution segment has been aggressively consolidating over the last few years with larger distributors acquiring smaller distributors. A large portion of our product sales (66% and 65% during the years ended December 31, 2018 and 2017, respectively) was made to two large distributors. A large portion of our trade accounts receivable (72% as of December 31, 2018 and 69% as of December 31, 2017) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us,

including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us.

Gross margin on product sales: It is one of our goals to again achieve a gross margin (before related depreciation expenses) as a percentage of total sales close to 50% after the initial launch of new products. Depreciation expense will be a larger component of costs of goods sold for **Re-Tain™** than it is for **First Defense®** and gross margins generally improve over time. Many factors discussed in this report impact our costs of goods sold. There is a risk that we are not able to achieve our gross margin goals, which would adversely affect our operating results and could impact our future operating plans.

Product risks: The sale of our products is subject to production, financial, efficacy, regulatory, competitive and other market risks. Elevated standards to achieve and maintain regulatory compliance required to sell our products continue to evolve. Failure to achieve acceptable biological yields from our production processes can materially increase our costs of goods sold and reduce our production output, leading to an order backlog. We have experienced customer complaints pertaining to the gel tube format of the **First Defense®** product line about some product that has become compacted and not expressible. We believe these failures result from exposure of our original formula to excessive heat conditions. This is a risk to achieving and maintaining customer acceptance. The costs associated with replacing defective product are accounted for in costs of goods sold. We believe we have improved our formulation and production processes to prevent this problem going forward and are now incurring added costs to ship this product on dry ice. There is no assurance that we will continue to achieve market acceptance at a profitable price level or that we can continue to manufacture our products at a low enough cost to result in a sufficient gross margin to justify their continued manufacture and sale.

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Product liability: The manufacture and sale of our products entails a risk of product liability. Our exposure to product liability is mitigated to some extent by the fact that our products are principally directed towards the animal health market. We have maintained product liability insurance in an amount which we believe is reasonable in relation to our potential exposure in this area. We have no history of claims of this nature being made.

*Regulatory requirements for the **First Defense®** product line:* **First Defense®** is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991. As such, our operations are subject to periodic inspection by the USDA. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the "Reference Standard"). Due to the unique nature of the label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product. We expect to be subject to similar regulatory oversight risks in territories outside of the United States where we sell our products.

*Regulatory requirements for **Re-Tain™**:* The commercial introduction of this product in the United States will require us to obtain FDA approval. Completing the development through to approval of the NADA by the FDA involves risk. While four of the five required Technical Sections have been approved, the development process timeline has been extensive (approximately 19 years) and has involved multiple commercial production strategies. The Chemistry, Manufacturing and Controls Technical Section was submitted for the Nisin Drug Substance during the first quarter of 2019. The timeline for the Nisin Drug Product submission defines the critical path to product approval. To reduce the risk associated with this process, we have met with the FDA on multiple occasions to align on filing strategy and requirements. We have disclosed a timeline of events that could lead to potential approval during the first half of 2020. However, there remains a risk that approval could be delayed or not obtained. We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Re-Tain™**, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. International regulatory approvals would be required for sales outside of the United States. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage in that territory. However, the assigned milk discard period may be shorter for our product than it is for other products on the market in Europe.

Economics of the dairy and beef industries:

The January count of all cattle and calves in the United States had steadily declined from 97,000,000 as of January 1, 2007 to 88,500,000 as of January 1, 2014. Then this figure increased to 89,100,000 as of January 1, 2015, to

91,900,000 as of January 1, 2016, to 93,700,000 as of January 1, 2017, to 94,300,000 as of January 1, 2018 and to 94,800,000 as of January 1, 2019, which is 0.5% higher than at January 1, 2018.

From 1998 through 2018, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 (2004) to the high of 9,392,000 (2017). The monthly average for 2018 decreased slightly to 9,385,000.

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The Class III milk price (an industry benchmark that reflects the value of product used to make cheese) is an important indicator because it defines our customers' revenue level. This annual average milk price level (measured in dollars per hundred pounds of milk) reached its highest point ever during 2014 at $22.34 (peaking at $24.60 in September 2014) since these prices were first reported in 1980. The 2014 high price for milk corresponds to a low count of cattle and calves of 88,500,000 on January 1, 2014 and an average annual U.S. dairy herd size of 9,256,000 during 2014. This average annual herd size from 1998 to 2013 was always lower than the 2014 level (except for during 2008), and since 2014 this average annual herd size has always been higher than the 2014 level. This strong milk price level during 2014 declined to the average of $15.80 during 2015 and further declined to $14.87 during 2016, but increased by 9% to $16.17 during 2017 and then declined by 10% to $14.61 during 2018. The low price level in 2018 is very problematic to the profitability of our customers. The recent annual fluctuations in this milk price level are demonstrated in the following table:

Average Class III Milk Price for the Year Ended December 31,		(Decrease) Increase	
2014	**2015**		
$22.34	$ 15.80	(29	%)
2015	**2016**		
$15.80	$ 14.87	(6	%)
2016	**2017**		
$14.87	$ 16.17	9	%
2017	**2018**		
$16.17	$ 14.61	(10	%)

The actual level of milk prices may be less important than its level relative to feed costs. One measure of this relationship is known as the milk-to-feed price ratio, which represents the amount of feed that one pound of milk can buy. The annual average for this ratio of 1.52 in 2012 was the lowest recorded since this ratio was first reported in 1985. The highest annual average this ratio has reached since 1985 was 3.64 in 1987. Since this ratio reached 3.24 in 2005, it has not exceeded 3.0. The annual average of 2.54 for 2014 was the highest this ratio has been since it was 2.81 in 2007. This ratio dropped 16% from 2017 to an annual average of 2.04 during 2018. The annual average has not been lower than this level since 2013. An increase in feed costs also has a negative impact on the beef industry. The following table demonstrates the annual volatility and the low values of this ratio recently:

Average Milk-To-Feed Price

Ratio for the Year Ended December 31,		(Decrease) Increase	
2014	**2015**		
2.54	2.14	(16	%)
2015	**2016**		
2.14	2.26	6	%
2016	**2017**		
2.26	2.42	7	%
2017	**2018**		
2.42	2.04	(16	%)

While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, the price for milk is also influenced by very volatile international demand for milk products.

The all-time high value (annual average) for a milk cow was $1,993 during 2015. Since then, this annual average value has steadily declined to $1,358 during 2018. The 2018 value represents a 32%, or $635, decrease from the 2015 high.

The industry data referred to above is compiled from USDA databases. Additionally, the value of newborn bull calves had risen to the unusually high level of approximately $300 to $400 during 2015 but has declined to very little presently, depending on region.

Given our focus on the dairy and beef industries, the volatile market conditions and the resulting financial insecurities of our primary end users are risks to our ability to maintain and grow sales at a profitable level. These factors also heighten the challenge of selling premium-priced animal health products (such as **Tri-Shield First Defense®** and **Re-Tain™**) into the dairy market.

Product development risks: The development of new products is subject to financial, scientific, regulatory, and market risks. Our current business growth strategy relies heavily on the development of **Re-Tain™**, our new product to treat subclinical mastitis, which has required (and will continue to require) a substantial investment of capital resources and personnel. Our efforts will be subject to inspection and approval by the FDA. There is no assurance whether or when we will obtain all of the data necessary to support regulatory approval for this product.

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Risks associated with our funding strategy for ***Re-Tain™****:* Producing our pharmaceutical-grade Nisin at commercial-scale is the most critical action in front of us on our path to U.S. regulatory approval for this product. Having completed construction of the production facility described elsewhere in this report at a cost of approximately $20.8 million, we will continue to incur product development expenses to operate this facility. We do not know whether we will receive the necessary regulatory approvals to manufacture and sell the product, or whether the product will achieve market acceptance and profitability. The additional debt we incurred to fund this project will significantly increase our debt service costs going forward. These loans are subject to certain financial covenants. Absent sufficient sales of **Re-Tain™** at a profitable gross margin, we would be required to fund all debt service costs from sales of the **First Defense®** product line, which would reduce, and could eliminate, our expected profitability going forward and significantly reduce our cash flows. As discussed elsewhere in this report, we may incur additional capital costs to construct our own aseptic filling capability for **Re-Tain™** which would magnify the risks detailed in this paragraph.

Uncertainty of market size and product sales estimates for ***Re-Tain™****:* Estimating the size of the market for any new product is subject to numerous uncertainties. Some of the uncertainties surrounding our product include market acceptance, the development of the subclinical mastitis treatment market, the effect of a premium selling price on market penetration, competition from existing products sold by substantially larger competitors, the risk of competition from other new products, cost of manufacture and integration of milk from treated cows with susceptible cheese starter cultures. Given what we believe to be reasonable assumptions, we estimate that the market potential for first year sales of our new product could be approximately $5.8 million and could grow to approximately $36.1 million during the fifth year after market launch. The amount of sales that we can capture from this estimated market potential and the timing of when this can be achieved is very difficult to know, and the actual size of the market for our new product may differ materially from our estimates (up or down). We expect the Drug Substance production facility that we have constructed to have production capacity to meet approximately $10 million in annual sales. Our new facility is designed to have enough room to add a second fermentation and recovery portion of the production line to be purchased and installed at the cost of approximately $7 million to effectively double production output. However, we are considering the strategic alternative of using this available space to perform the final formulation, aseptic filling and final packaging services in-house.

Exposure to debt service obligations and debt covenants: Rising interest rates could negatively affect our operating results due to the large portion of our borrowings that bear interest at variable rates (which were not effectively converted to fixed rate obligations through interest rate swaps) as well as by increasing dairy farmers' operating costs and thus putting further financial pressure on an already stressed business sector. Based on the terms of our bank debt agreements effective as of December 31, 2018, we are required by bank debt covenant to maintain at least $2 million of otherwise unrestricted cash, cash equivalents and short-term investments. This requirement effectively reduces the availability of our liquid assets for operational needs and creates a risk of non-compliance.

Competition from others: Many of our competitors are significantly larger and more diversified in the relevant markets than we are and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. Elanco, Merck and Zoetis, among other companies, sell products that compete directly with the **First Defense®** product line in preventing scours in newborn calves. The scours product sold by Zoetis sells for approximately half the price of our product, but it does not have an *E. coli* claim (which ours does). The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Boehringer Ingelheim, Merck and Zoetis. The mastitis products sold by these large companies are well established in the market and are priced lower than what we expect for our product, but all of them involve traditional antibiotics and are sold subject to a requirement to discard milk during and for a period of time after treatment. There is no assurance that our product will compete successfully in this market. We may not be aware of other companies that compete with us or intend to compete with us in the future.

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Access to raw materials and contract manufacturing services: Our objective is to maintain more than one source of supply for the components used to manufacture and test our products that we obtain from third parties. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. We have significantly increased the number of farms from which we purchase colostrum. The loss of farms from which we buy raw material for the **First Defense®**product line could make it difficult for us to produce enough inventory to meet customer demand. The specific antibodies that we purify from colostrum for the **First Defense®**product line are not readily available from other sources. We are and will be dependent on our manufacturing facilities and operations in Portland for the production of the **First Defense®**product line and Nisin. We are and will be dependent on Plas-Pak Industries, Inc. (now owned by Nordson Corporation) for the supply of the syringes used for our gel tube format of **Dual-Force™ First Defense®**, **Tri-Shield First Defense®**and **Re-Tain™**. The supply contract covering the mastitis syringes has been extended to January 1, 2024. We expect to be dependent on a contract with Norbrook for the final formulation, aseptic filling and final packaging of our Nisin Drug Substance into Drug Product unless we find an alternative contractor or invest to perform these services in-house. Norbrook may have the right to terminate the agreement in December 2019 and charge us a $100,000 termination fee if (as we anticipate) we do not receive FDA approval for **Re-Tain™** by that date. We have been and are currently negotiating certain contract modifications and a term extension with Norbrook. There is no assurance that this negotiation will be successful for us. Due to the potential loss of this contract as discussed elsewhere in this report, we are evaluating alternative sources for these services (including a potential investment in our own facility to perform these services internally) for potential use post-approval, but given the requirement that such a facility be inspected and approved by the FDA, it could be costly and time-consuming to find and qualify an adequate alternative source for these services. Also, our potential alternative options for these services are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e. beta lactams). Not many potential sites meet this requirement. There can be no assurance that we would be able to identify and reach contractual terms with a duly licensed/certified provider of these services, as applicable, if our relationship with Norbrook were to be terminated or, if we were able to do so, how quickly that could occur and on what terms. Such a shift could result in significant production interruptions, delay in market launch, significantly increased cost of goods sold and reduced margins, the effects of which could be material and adverse to us. Any significant damage to or other disruption in the services at any of these third-party facilities (including due to regulatory non-compliance) could adversely affect the production of inventory and result in significant added expenses and potential loss of future sales.

Production Capacity Constraints: The failure to meet market demand for our products discussed elsewhere in this report is a risk to our business. Our plan to continue to expand the **First Defense®** product line requires ongoing review of equipment capacity and utilization across the manufacturing value stream at the 56 Evergreen Drive facility as well as assessment of functional obsolescence and reliability of equipment. It is anticipated that we will need to add a third freeze dryer to the equipment train for the **First Defense®** product line over the next two or three years at a cost of approximately $1-$2 million in order to meet customer demand. Our current two freeze dryers are functioning at a utilization rate of approximately 85%. Additional liquid processing equipment may be required at a cost of approximately $1-$2 million. There is a risk that we will not be able to achieve our production capacity growth objectives on a timely basis.

Small size; dependence on key personnel: We are a small company with 51 employees (including 4 part-time employees). As such, we rely on certain key employees to support multiple operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained. Our competitive position will be highly influenced by our ability to attract and retain key scientific, manufacturing, managerial and sales and marketing personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products, to maintain regulatory compliance with current products and to continue to profitably sell our current products. We continue to monitor our network of independent distributors to maintain our competitive position.

Failure to protect intellectual property: In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. Instead, we have sought (and may seek in the future) to maintain the confidentiality of any relevant proprietary technology through operational safeguards and contractual agreements. Reliance upon trade secret, rather than patent, protection may cause us to be vulnerable to competitors who successfully replicate our manufacturing techniques and processes. Additionally, there can be no assurance that others may not independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Other companies may have filed patent applications and may have been issued patents involving products or technologies potentially useful to us or necessary for us to commercialize our products or achieve our business goals. There can be no assurance that we will be able to obtain licenses to such patents on terms that are acceptable. There is also a risk that competitors could challenge the claims in patents that have been issued to us.

Cost burdens of our reporting obligations as a public company: Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws and the provisions of the Sarbanes-Oxley Act of 2002.

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Exposure to risks associated with the financial downturn and economic instability: Positive indications about the health of the U.S. economy could prove temporary, and a downturn could occur. Some observers believe that the housing market remains problematic for the overall U.S. economy, the United States has taken on too much national debt and the equity markets are overvalued. Interest rates are trending higher, which could adversely affect us and the general economy and our customers. This extraordinary period of instability in the U.S. economy and the financial markets has been troubling for many Americans and businesses. The dairy market is presently under extreme economic pressure, causing many of our customers to lose money or only earn minimal profits. A small percentage reduction in the export of dairy products results in a significant drop in the domestic price of milk. A combination of the conditions, trends and concerns summarized above could have a corresponding negative effect on our business and operations, including the demand for our products in the U.S. market and our ability to penetrate or maintain a profitable presence in international markets.

Bovine diseases: The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) presents a risk to us and our customers. Documented cases of BSE in the United States have led to an overall tightening of regulations pertaining to ingredients of animal origin, especially bovine. The **First Defense®** product line is manufactured from bovine milk (colostrum), which is not considered a BSE risk material. Future regulatory action to increase protection of the human food supply could affect the **First Defense®** product line, although presently we do not anticipate that this will be the case.

Biological terrorism: The threat of biological terrorism is a risk to both the economic health of our customers and our ability to economically acquire and collect good quality raw material from our contract farms. Any act of widespread bioterrorism against the dairy industry could adversely affect our operations.

Certain provisions might discourage, delay or prevent a change in control of our Company or changes in our management: Provisions of our certificate of incorporation, our bylaws, our Common Stock Rights Plan or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

limitations on the removal of directors; advance notice requirements for stockholder proposals and nominations;

the ability of our Board of Directors to alter or repeal our bylaws;

the ability of our Board of Directors to refuse to redeem rights issued under our Common Stock Rights Plan or otherwise to limit or suspend its operation that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors; and

Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could depress the trading price of our common stock or limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood of obtaining a premium for our common stock in an acquisition.

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Stock market valuation and liquidity: Our common stock trades on The Nasdaq Stock Market (Nasdaq: ICCC). Our average daily trading volume (although it has increased recently) is lower than the volume for most other companies and the bid/ask stock price spread can be larger and prices can be volatile, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire. There are companies in the animal health sector with market capitalization values that greatly exceed our current market capitalization of approximately $37,982,000 as of March 18, 2019. We currently (for the year ended December 31, 2018) have annual product sales of approximately $11,000,000. Before gross margin from the sale of new products is achieved, our market capitalization may be heavily dependent on the perceived potential for growth from our products under development.

No expectation to pay any dividends or repurchase stock for the foreseeable future: We do not anticipate paying any dividends to, or repurchasing stock from, our stockholders for the foreseeable future. Instead, we expect to use cash to fund product development costs and investments in our facility and production equipment, and to increase our working capital and to reduce debt. Stockholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws, current and anticipated needs for liquidity and other factors our Board of Directors deems relevant.

Possible dilution: We may need again to access the capital markets and issue additional common stock in order to fund our growth objectives, as described elsewhere in this report. Such issuances could have a dilutive effect on our existing stockholders.

ITEM 1B — UNRESOLVED STAFF COMMENTS

None

ITEM 2 — PROPERTIES

We own a 35,000 square foot (approximately) building at 56 Evergreen Drive in Portland, Maine. We currently use this space for substantially all of our office, laboratory and manufacturing needs. When we originally purchased this building in 1993, its size was 15,000 square feet, including 5,000 square feet of unfinished space on the second floor.

In 2001, we completed a construction project that added approximately 5,200 square feet of new manufacturing space on the first floor and approximately 4,100 square feet of storage space on the second floor. In 2007, we built out the 5,000 square feet of unfinished space on the second floor into usable office space. After moving first floor offices into this new space on the second floor, we modified and expanded the laboratory space on the first floor and added approximately 2,500 additional square feet of storage space on the second floor. During 2009, we added 350 square feet of cold storage space connected to our first floor production area and added an additional 600 square feet to the second floor storage area. During the first quarter of 2015, we completed construction of a two-story addition connected to our facility to provide us with approximately 7,100 additional square feet for cold storage, production and warehouse space for our operations.

During the fourth quarter of 2015, we exercised an option to acquire land at 33 Caddie Lane in Portland, Maine which is nearby to our facility at 56 Evergreen Drive, on which we initiated construction of our production facility for purified Nisin during the third quarter of 2016. During the fourth quarter of 2017, we obtained a certificate of occupancy from the City of Portland for our 16,202 square foot (9,803 on the first floor and 6,399 on the second floor) Drug Substance production facility.

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During 2016, we rented approximately 3,266 square feet in Minnesota on a short-term basis, where we formulated our gel tube delivery format of **First Defense Technology**® and certain private label products. This lease expired during the first quarter of 2017, and we no longer utilize this space. The manufacturing of this product line was transferred to the Portland facility during the first quarter of 2017.

During the first quarter of 2017, we purchased a 4,114 square foot facility adjacent to the Drug Substance production facility. We are using this warehouse space primarily for storage of inventory, materials and equipment.

Previously, we rented approximately 640 square feet of office and warehouse space in New York to support our farm operations. During the first quarter of 2017, we exited this property and entered into a renewable, two-year lease for approximately 1,350 square feet of office, warehouse and garage space nearby. This lease has been extended through February of 2021.